

REMARKS

35 U.S.C. § 103: Claims 1, 3 and 4

Claims 1, 3 and 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Heinke et al. In particular, the Examiner notes:

Heinke et al. disclose an [sic] coil (1) having proximal and distal ends that are radially inward relative to the center section. However, Heinke et al. do not disclose the detachable ends. Mariant et al. teach of this element (see Figure 14) in the same field of endeavor for the purpose of allowing proper placement of the coil. It would have been obvious to one skilled in the art at the time of the invention to have placed the attachment means taught by Mariant at [sic] al. onto the Heinke et al. device in order to allow proper and controlled placement of the coil.

Regarding Applicant' arguments, "immediately adjacent" appears to mean "beside". The Heinke et al. reference clearly shows this feature. Regarding the arguments of combination, the problem of maintaining and controlling a coil is well known in the prior art. See the Sepetka '437, Engelson '916 and Palermo '071 references. Mariant et al. teaches of TWO [sic] techniques to aid in the placement of the coil.

Applicants respectfully disagree.

Please note two features appearing in element (d) of claim 1 at lines 8-12: first, the coil is wound into a second diameter smaller than the first diameter at the proximal and distal ends; second, the proximal and distal ends are positioned radially inwardly of the immediately adjacent first diameter.

To illustrate these two features, please refer to the figures below.

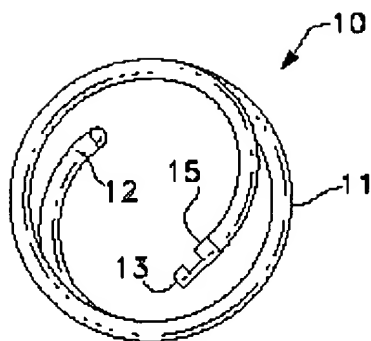


Figure A

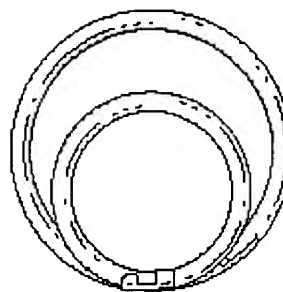


Figure B

Each figure represents a coil comprising a multiplicity of windings viewed from the proximal end. For the purpose of the current rejection, the coil of Figures A and B could also be viewed from the distal end; it is immaterial which end is presented to the viewer.

Figure A represents a coil identical to that shown in Figure 2 of the present pending application. Note that this embodiment meets all the limitations of pending claim 1, including the two mentioned above: the coil is wound into a second smaller diameter at each of the distal and proximal ends, and the distal and proximal ends 12 and 13 are positioned radially inwardly of the immediately adjacent first diameter 11.

Figure B, however, is an example of a coil that meets all of the limitations of claim 1 *except* for one: the proximal (or distal) end is not “positioned radially inwardly of” the immediately adjacent first diameter. Note that this is true despite the fact that the coil of Figure B meets the claim 1 limitation requiring the coil to be wound into a second, smaller diameter turn at the proximal (or distal) end.

Not only does the coil of Figure B fail to meet all the limitations of claim 1, it also does not serve several purposes of the present invention. There is a much greater likelihood that the proximal (or distal) end of the Figure B coil will catch or snag the interior or intima of a blood vessel or aneurysm, with an accordingly increased likelihood of morbidity and even mortality. In addition, release of the Figure B coil close to the vessel wall raises the potential that the vessel wall will interfere with uncoupling. The location of the end of the Figure B coil on the periphery of the coil's secondary structure also has the potential for serving as the *situs* for the formation of a thrombus and its attendant downstream problems.

Note that Figure 3 of the present application is the coil of Figure 2 (in the present application) and Figure A (above) viewed from the side. In this view, it is difficult, if not impossible, to ascertain whether the coil meets the "positioned radially inwardly" limitation of claim 1. In other words, the view of the inventive coil shown in Figure 3 of the present invention could not only be the coil of Figure A, but it also could represent the coil shown in Figure B.

Turning now to German patent 3,203,410 ("Heinke"), Applicants respectfully submit that this reference comes nowhere close to serving as a basis to render claim 1 obvious. In particular, the Figures 7-8 views of Heinke and the translation of the accompanying text not only do not show the "positioned radially inwardly" limitation discussed above, it never even suggests such a solution nor the motivation for one.

In particular, the Examiner takes the view that the coil shown in Figures 7 and 8 of Heinke meets each limitation of claim 1 (except for the detachable end, which is the reason the Mariant et al. reference is cited). Note that each end of the Figure 8 coil 1 is marked by reference numeral 2. As discussed at page 3 of Heinke in conjunction with the close-up of the coil shown in Figures 1 and 2, a "thickened head 2 is arranged at one end or both ends of the

wire coil". There is no other discussion regarding these ends, and the only mention of Figures 7 and 8 in the translated text is a single description on page 3 and later a brief phrase on page 4 reciting that the occlusion body can be in a "barrel-shaped configuration". There is no discussion of the orientation of the proximal or distal ends of this coil.

The Examiner seems to be relying solely on Figures 7 and 8 to conclude that this side view of their coil shows the proximal and distal ends turn radially inwardly. Applicants respectfully submit that the Examiner seems to be confusing the two element (d) limitations of claim 1 detailed above. Applicants believe the Examiner has incorrectly concluded that because the diameter of the windings of the Figures 7-8 coil decrease as one moves either proximally or distally from the center of the coil, it must necessarily follow that the proximal and distal ends are radially inturned. This is simply not true.

First, as shown above in the examples of Figures A and B, it *is* possible for a coil to have a smaller proximal or distal diameter winding yet *not* meet the limitation that the ends are radially inturned. Therefore, just because the Heinke coil in Figures 7 and 8 have a smaller proximal and distal diameter than the more interior windings has absolutely nothing to do with this limitation.

Next, it is simply impossible to tell, given the side view of the coil shown in Figure 7 and 8, whether this "positioned radially inwardly" limitation is met. As fully discussed above with respect to this phenomenon in the present application and the Figure 3 side view, unless there is an end view (similar to Figures A or B above) of the Heinke coil shown in Figures 7 and 8, one of ordinary skill simply cannot tell if the distal end and the first coupling member at the proximal end are positioned radially inwardly of the immediately adjacent first diameter. Applicants respectfully challenge the Examiner to show otherwise. Applicants believe that the Examiner's

conclusion in the present rejection to the contrary is not only factually incorrect but unsupported by logic.

In rejecting a claim under 35 U.S.C. § 103(a), it is the burden of the Examiner to establish a *prima facie* case of obviousness. Only if such a case is made does the burden shift to Applicants to rebut it.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. Alternatively, even if such a *prima facie* case were made, Applicants respectfully submit that the arguments made in this response are clearly sufficient to rebut and overcome such a *prima facie* case.

Therefore, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 103(a) is improper and request that it be withdrawn. Applicants also most respectfully submit that as claims 3 and 4 depend from claim 1, their rejection is also improper and should be withdrawn.

SUMMARY

Applicants wish to thank the Examiner for participating in the telephone interview with Applicants' representative, William Revelos, on August 11, 1999.


Applicants believe that the arguments submitted above are fully responsive and overcome the present outstanding rejection. Accordingly, Applicants respectfully request that the present rejection be withdrawn and pending claims 1, 3 and 4 be allowed.

Should the Examiner have any additional requests or a desire to discuss the details of the invention in greater detail, he is invited to contact Applicants' attorney at the number listed below.

Respectfully submitted,

Dated: August 30, 1999

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